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10/523,166

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Gerd Seibold

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71040 7590 10/10/2007  
LUCE, FORWARD, HAMILTON & SCRIPPS  
11988 EL CAMINO REAL, SUITE 200  
SAN DIEGO, CA 92130

EXAMINER

BLATT, ERIC D

ART UNIT

PAPER NUMBER

4132

MAIL DATE

DELIVERY MODE

10/10/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/523,166

Applicant(s)

SEIBOLD ET AL.

Examiner

Eric Blatt

Art Unit

3709

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 1-27-2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 25-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 30-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

KHOI H. TRAN  
SUPERVISORY PATENT EXAMINER

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-24 and 30-40, drawn to a device for sealing a puncture.

Group II, claim(s) 25-29, drawn to a device for sealing a puncture.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group II positively recites only a nut coupled to a bolt wherein the nut comprises a self-expanding disk and the bolt comprises a second self-expanding disk. Neither of these positively claimed elements can be considered a special technical feature as they were known in the art prior to the invention. (See Kotula et al., US 5,725,552)

During a telephone conversation with Franco Serafini on September 19, 2007 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-24 and 30-40. Affirmation of this election must be made by applicant in

replying to this Office action. Claims 25-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6, 7, 9, 11, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaw et al. (US 6,080,182).

Regarding claim 1, 4, 6, 7, 9, 11, and 40 Shaw discloses a device for sealing a puncture extending through tissue proximal to an interior vessel surface, the device comprising:

- a first disk (first end of sealing device 132) having a self-expanding frame that forms a plurality of petals (Figures 8A-8F); and

- a proximal element comprising a second disk (second end of sealing device 132) having a second self-expanding frame coupled to the first disk, wherein the device has a retracted delivery configuration adapted for delivery to the puncture, and a deployed configuration in which the first disk is adapted to engage and substantially conform to the interior vessel surface, and the proximal element is configured to engage the tissue. (Figures 22A-22G)
- a minimally invasive delivery apparatus (Figure 36) comprising first and second delivery elements 216, 222 configured to at least selectively limit distal translation of the first delivery element with respect to the second delivery element so that only the first disk is extended out of the minimally invasive delivery apparatus. (Column 17, Lines 16-30)
- at least one delivery shaft 80 configured to facilitate coupling of the first disk to the proximal element. (Figures 22A-22-G)
- at least one delivery element constrained to translate a maximum distal depth. (Figure 36, Column 17, Lines 16-30)
- the proximal element comprises a spring (Figure 40D); and
- a membrane encasing at least the self-expanding frame of the first disk. (See Abstract)

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2-3, 5, 8, 10, 13-16, 18-24, and 30-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw et al. (US 6,080,182) in view of Stevens et al. (US 5,797,960).

Regarding claims 2-3, 5, 8, 14-16, 18-23, and 24, Shaw discloses a device for sealing a puncture extending through tissue proximal to an interior vessel surface, the device comprising:

- a first disk (first end of sealing device 132) having a self-expanding frame that forms a plurality of petals (Figures 8A-8F); and
- a proximal element comprising a second disk (second end of sealing device 132) having a second self-expanding frame coupled to the first disk, wherein the device has a retracted delivery configuration adapted for delivery to the puncture, and a deployed configuration in which the first disk and second disks are adapted to engage and substantially conform to the interior vessel surface, and the proximal element is configured to engage the tissue (Figures 22A-22G)
- the second self-expanding frame forms a plurality of petals (Figures 8A-F)

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- a minimally invasive delivery apparatus (Figure 36) comprising first and second delivery elements 216, 222 configured to at least selectively limit distal translation of the first delivery element with respect to the second delivery element so that only the first disk is extended out of the minimally invasive delivery apparatus. (Column 17, Lines 16-30)
- at least one delivery shaft 80 configured to facilitate coupling of the first disk to the proximal element. (Figures 22A-22-G)
- at least one delivery element constrained to translate a maximum distal depth. (Figure 36, Column 17, Lines 16-30)
- the proximal element comprises a spring (Figure 40D); and
- a membrane encasing at least the self-expanding frame of the first disk. (See Abstract)

Shaw does not disclose:

- the device, including the first and second disks, are configured to be released from engagement with the interior vessel surface after deployment of the device, thereby permitting the device to be repositioned.
- the first disk is attached to a nut and the second disk is attached to a bolt, the nut configured to be releasably coupled to the bolt.
- the at least one delivery shaft is configured to facilitate coupling and decoupling of the first disk from the proximal element.

Stevens discloses a system for sealing a puncture comprising:

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- a first disk attached to a nut and the second disk attached to a bolt, the nut configured to be releasably coupled to the bolt (Figures 10-14, Columns 4-5, Column 20)
- at least one delivery shaft is configured to facilitate coupling and decoupling of the first disk from the proximal element (Figures 10-14, Columns 4-5, Column 20)
- the sealing device, including the first and second disks, are configured to be released from engagement with the interior vessel surface after deployment of the device, thereby permitting the device to be repositioned. (Figures 10-14, Columns 4-5, 20, 25)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Shaw by providing the attachment mechanism disclosed in Stevens for purposes such as allowing the sealing device to be repositioned if the first deployment position is unsatisfactory as taught by Stevens. (Column 25, Lines 4-17)

Regarding claims 10,13, 30-35, and 37-39, 37, Shaw does not disclose:

- at least part of the device is biodegradable
- one or both of the first disk and the proximal element comprises barbs, hooks, sharp edges, or roughened surfaces.

Stevens discloses:

- at least part of the device is biodegradable (Column 22, 18-23)
- one or both of the first disk and the proximal element comprises barbs, hooks, sharp edges, or roughened surfaces. (Figures 10-15, Column 20, Lines 27-48)



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It would have been obvious to one of ordinary skill at the time of the invention to further modify the apparatus of Shaw by having at least part of the device be biodegradable for purposes such as allowing components to biodegrade as the tissue heals as taught by Stevens. Additionally, it would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the apparatus of Shaw by providing barbs, hooks, or sharp edges to aid the closure device in engaging the vessels walls as taught by Stevens.

Regarding claim 36, Shaw discloses a device for sealing a puncture extending through tissue proximal to an interior vessel surface, the device comprising:

- a first disk (first end of sealing device 132) having a self-expanding frame that forms a plurality of petals (Figures 8A-8F); and
- a proximal element comprising a second disk (second end of sealing device 132)
- wherein the proximal element comprises a spring. (Figure 40D)

Shaw does not disclose:

- at least part of the device is biodegradable.

Stevens discloses:

- at least part of the device is biodegradable. (Column 22, 18-23)

It would have been obvious to one of ordinary skill at the time of the invention to further modify the apparatus of Shaw by having at least part of the device be biodegradable for purposes such as allowing components to biodegrade as the tissue heals as taught by Stevens.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw et al. (US 6,080,182) in view of Van Tassel et al. (US 6,949,113).

Regarding claim 12, Shaw discloses all elements of claim 12 as previously discussed except a coagulant-enhancing agent that is disposed on one or both of the first disk and the proximal element. Van Tassel discloses device for sealing an opening in a blood vessel comprising a coagulant-enhancing agent that is disposed on a disk. (Column 12, Lines 20-24) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Shaw by providing a coagulant-enhancing agent that is disposed on one or both of the first disk and the proximal element to prevent blood from passing through the sealed puncture as taught by Van Tassel.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw et al. (US 6,080,182) in view of Stevens et al. (US 5,797,960) as applied to claim 14 above, and further in view of Van Tassel et al. (US 6,949,113).

Regarding claim 17, Shaw discloses all elements of claim 17 as previously discussed except a coagulant-enhancing agent that is disposed on one or both of the first disk and the proximal element. Van Tassel discloses device for sealing an opening in a blood vessel comprising a coagulant-enhancing agent that is disposed

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on a disk. (Column 12, Lines 20-24) It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the apparatus of Shaw by providing a coagulant-enhancing agent that is disposed on one or both of the first disk and the proximal element to prevent blood from passing through the sealed puncture as taught by Van Tassel.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following documents contain relevant designs:

Saadat, Vahid et al.	US 20050277983 A1
Thill; Gary A. et al.	US 6214029 B1
Das; Gladwin S.	US 5334217 A
Cope, Constantin	US 20030191497 A1
Anson; Anthony Walter et al.	US 7223280 B2
Yang, Dachuan et al.	US 20030055455 A1
Sevrain; Lionel C. et al.	US 6258091 B1
Yang; Dachuan et al.	US 6596013 B2
Girton; Timothy	US 6537300 B2
Gainor; John et al.	US 6911037 B2
Thill; Gary A.	US 6551344 B2
Amplatz; Kurt et al.	US 5944738 A

Kotula; Frank et al.

US 5725552 A

Marks; Lloyd A.

US 5108420 A

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571) 272-9735. The examiner can normally be reached on Monday to Friday, 7:30 A.M. to 5:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Khoi Tran can be reached on (571) 272-6919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Blatt  
571-272-9735

KHOI H. TRAN  
SUPERVISORY PATENT EXAMINER

